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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,377	03/01/2001	Aladar A Szalay	11785-3	8166

7590 06/28/2005

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,377	SZALAY ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date all 11/24/04, 9/14/04 & 3/1/01
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 16, 24, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 16, 24 and 32 recite the limitation "where detecting any fluorescence from the donor luciferase is performed using spectrofluorometry" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The present specification fails to describe such limitation.

Please also check the spelling of "spectrofluoro***metery***" on those claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-15, 17-23, 25-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (US 6,232,107).

Bryan teaches methods of using non-radioactive energy reactions using Green Fluorophore Proteins (GFPs) and luciferases and FRET (fluorescence resonance energy transfer) assays. In FRET assays, energy transfer that are carried out between a donor luminescent label and an acceptor label. Recombinant host cells containing heterologous nucleic acid encoding a Renilla GFP are also provided. The recombinant cells are produced by transfection with DNA encoding a Renilla GFP or by introduction of RNA transcripts of DNA encoding a Renilla GFP. The cells contain DNA or RNA encoding a Renilla GFP also express the recombinant Renilla polypeptide. The cells are selected to express functional GFPs that retain the ability to fluorescence and that are not toxic to the host cell. Cells may also include heterologous nucleic acid encoding a component of a bioluminescence generating system such as a photoprotein or a luciferase. The nucleic acid encoding the luciferase is isolated from Renilla luciferase. The preferred cells that express functional luciferase and/or GFP which may be used alone or in conjunction with a bioluminescence generating system, in cell-based assays and screening methods are animal cells (mammalian cells), plant cells, bacteria, yeasts, fungi, insect cells. (see col. 10, line 8-col. 11, line 42). Bryan also teaches method for diagnosis and visualization of tissues or cells in vivo or in situ using two compositions. The first composition contains conjugates that include antibodies directed against tumor antigens conjugated to a component of the bioluminescence generating reaction, a luciferase. The second composition contains the remaining components of a bioluminescence generating system such as a GFP linked to a protein or other protein carrier. The interaction between the luciferase and the GFP is detected in vivo or in

vitro. (see col. 12, line 66-col. 13, line 17, lines 35-55; figure 11, col. 87, lines 35-63). Regarding claims 2, 10, 18 and 26, since Bryan teaches that isolated and purified nucleic acid molecules that encode a luciferases and GFPs and the proteins encoded thereby are provided, it is inherent the first protein complexed to a donor luciferase and the second protein complexed to an acceptor fluorophore comprises genetically engineering DNA and transferring the DNA to the living cell causing the cell to produce the first protein complexed to a donor luciferase and the second protein complexed to an acceptor fluorophore.(see col. 99, lines 37-48). For claims 5, 13, 21, and 29, Bryan teaches the donor luciferase is a Renilla luciferase. (see example 5). For claims 6, 7, 14, 15, 22, 23, 30 and 31, Bryan teaches the acceptor fluorophore is an Aequorea green fluorescence protein (GFP) (see col. 12, lines 20-22). For claims 17 and 25, Bryan teaches method for diagnosing disease using chip methodology. The chip includes an integrated photodetector that detects the photon emitted by bioluminescence generating system using luciferase encoded by the nucleic acid provided and/or GFP. A selected antibody specific for a bacterial antigen, is affixed to the surface of the chip. After contacting the chip with the sample, the chip is contacted with a second antibody linked to a GFP that are specific for the antigen. If the antigen is present, light will be generated and detected by the adjacent photodetector. (see col. 13, line 65-col. 14, line 19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 16, 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (US 6,232,107) in view of Brisson et al. (US 6,872,871).

Bryan has been discussed above.

However, Bryan fails to teach using spectrofluorometry to detect the fluorescence from the donor luciferase.

Brisson teaches an assay using a fluorescent compound as a label and measuring such fluorescence by spectrofluorometry. (see col. 6, lines 27-32).

It would have been obvious to one of ordinary skills in the art to use spectrofluorometry as taught by Brisson to measure the fluorescence in the method of Bryan since both references teach using a fluorescent label/compound in an assay and spectrofluorometry is known in the art for measuring fluorescence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
June 24, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/24/15